VALUE IN HEALTH 19 (2016) 516–519

Available online at www.sciencedirect.com

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journal homepage: www.elsevier.com/locate/jval

Considering Cost-Effectiveness in Cardiology Clinical Guidelines: Progress and Prospects

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ABSTRACT

Since the 1980s, when the American College of Cardiology (ACC) and the American Heart Association (AHA) established a joint task force to examine the use of cardiovascular procedures and therapies, cardiologists have been leaders in the development of clinical practice guidelines. The ACC/AHA guidelines development process has evolved considerably over the last 30 or more years. Guidelines now focus on clinical conditions, such as angina, instead of procedures, such as bypass surgery. There is a formal organizational structure, with dedicated staff, a standing committee on practice guidelines, and specific panels of volunteer experts on each topic. This process tightly manages conflicts of interest and strives for evidence-based, as opposed to opinion-based, guidelines, with a clear citation of the supporting evidence. Traditional clinical guidelines consider only what is best for the individual patient, and have explicitly *not* considered the cost to society. Nevertheless, in many guidelines development meetings, high cost was implicitly considered: if a procedure was extremely costly, the evidence needed to be very strong. The Guidelines Committee recognized that cost considerations ought to be made more transparent, and that the evidence on economic value should be explicitly cited when available. These considerations were formalized by a recent white paper on incorporating economic considerations into ACC/AHA guidelines. In considering value, it is necessary to assess the quality of the evidence as well as to define levels of value. The next ACC/AHA guideline will incorporate value as a part of its recommendations. This will be an evidence-based process in which published economic assessments relating to key questions will be reviewed.

Keywords: cardiology, clinical practice guidelines, cost, cost-effectiveness analysis, value, value frameworks.

Background

Cardiovascular disease is the leading cause of death and a major cause of disability in the United States. There is a great interest in cost-effectiveness in cardiology because of the multiple innovations in this field, with many new therapies, new procedures, and novel implantable devices. These innovations are often quite costly, and they typically diffuse widely because the clinical dynamic is that when a new procedure is found to work in high-risk patients with heart disease, it tends to be extended to lower and lower risk patient groups as well. The broad use of costly new therapies is encouraged by clinicians' concerns that if someone were to have a heart attack or die, and clinicians had not applied the latest therapies, they would regret it greatly and potentially be liable for lawsuits. The consequence is that cardiologists tend to be aggressive in using costly therapies in borderline situations.

Cardiology is numbers-driven and has a very robust culture of conducting randomized clinical trials to evaluate new therapies, often enrolling tens of thousands of patients to detect very small differences in the rates of major outcomes. There are also several large clinical registries for important cardiac diseases, such as the National Cardiovascular Data Registry's Percutaneous Coronary Intervention Registry for coronary angioplasty. Clinical registries for surgery, devices, and procedures document how treatments are being used in practice and what outcomes they have in real-world populations. So cardiologists have a strong culture of trying to figure out what they are doing and whether they are improving outcomes.

The general public has had a long-standing belief that too much money is being spent in cardiology, and therefore cardiologists have had to justify what they were doing. Consequently, cardiologists have often performed economic evaluations to assess the impact of new therapies on cost as well as on clinical outcomes. There are a number of economic analyses performed alongside randomized trials, such as the landmark study comparing streptokinase with tissue plasminogen activator [1]. In addition to many trial-based economic analyses, many simulation models and cost-effectiveness analyses have been performed, underscoring the strong tradition of an economic analysis as well as a clinical trials analysis in cardiology.

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http://dx.doi.org/10.1016/j.jval.2016.04.019

Clinical Practice Guidelines in Cardiology

Cardiologists have been leaders in the development of clinical practice guidelines. In 1980, the two major cardiovascular societies, the American College of Cardiology (ACC) and the American Heart Association (AHA), established a joint task force to examine the use of cardiovascular procedures and therapies. The very first clinical guideline was developed by the ACC/AHA in 1984 about indications for pacemakers, in response to concerns by Medicare and others that too many pacemakers were being implanted without good cause. In fact, Medicare did not want to pay for unnecessary pacemakers. So the ACC and the AHA established a guideline panel to consider what the clinical indications ought to be for implanting a pacemaker. The committee rated indications using an analogy to a traffic stoplight: a top-line recommendation that a pacemaker was indicated (a green light), a clear indication that a pacemaker was not indicated (a red light), and a zone of uncertainty in between (a yellow light). This three-level recommendation framework has endured in practice guidelines: generally positive (class I), generally negative (class III), and uncertain in the middle (class II).

From this early start and initial focus on specific procedures and devices, the ACC and AHA guidelines development process has evolved considerably over the last 30 or more years. Guidelines now focus on clinical conditions, such as angina and high blood pressure, instead of focusing on procedures, such as bypass surgery. Guidelines now have a formal organizational structure, with staff devoted to this task, a standing committee on practice guidelines, and specific panels of volunteer experts on each topic. This process also tightly manages conflicts of interest and strives for evidence-based, as opposed to opinion-based, guidelines, with a clear citation of the evidence backing up the various recommendations (e.g., "A" for multiple randomized trials).

Ten ACC/AHA guidelines were published in 2013 and 2014 (Table 1) covering a broad range of cardiovascular disease management. The guidelines, once published, are updated every 5 years, or sooner if major new evidence warrants it.

Figure 1 outlines the present framework for determining the class of recommendations. Class I indications are when benefit greatly exceeds the risk and therefore the procedure should be performed. Class II (a/b) indications are when the benefit is probably greater than the risk and the intervention would be reasonable, but that more studies would be helpful. Class III indications are when there is no benefit, and may be harm, and so the procedure should not be performed. Thus, the columns are the various classes of the recommendation with the strength of the recommendation. The rows outline the level of evidence. Level of evidence A is when multiple populations have been evaluated, typically through multiple randomized trials. Level of evidence B is when only limited populations have been examined, perhaps using data from a single trial or from registry studies. Level of evidence C is when very limited populations have been examined, perhaps when the evidence is based more on opinion and observation than on rigorous analysis. Every recommendation can be located in one of the categories on the grid, and a class I-A recommendation is the strongest one that can be made.

Table 1 – Recent ACC/AHA guidelines.

2014
Non–ST-segment acute coronary syndromes
Noncardiac surgery risk reduction
Stable ischemic heart disease
Atrial fibrillation
Valvular heart disease
2013
Cardiovascular risk in asymptomatic adults
Cholesterol treatment
Overweight and obesity
Heart failure
Peripheral arterial disease

ACC/AHA, American College of Cardiology/American Heart Association.

Incorporating Value and Cost into the Guidelines

Traditional clinical guidelines consider only what is best for the individual patient, and have explicitly *not* considered the cost to society. Nevertheless, in many guidelines development meetings, high cost was the elephant in the room. If a procedure was extremely costly, there was a feeling that the evidence ought to be very strong before it could be recommended. The Guidelines Committee recognized that cost considerations ought to be made more transparent and that the evidence on economic value should be explicitly cited when available. These considerations were formalized by a recent white paper on incorporating economic considerations into ACC/AHA guidelines [2]. The key statement in the proposal was:

> Traditionally, resource utilization and value considerations have been explicitly excluded from practice guidelines and performance measures formulations, although they often are implicitly considered. This document challenges this historical policy … there is growing recognition of the need for more explicit and transparent assessment of the value of health care.

Therefore, guidelines should "include an assessment of value when data are available and reliable," and for class I and class IIa recommendations, a value assessment should be included [2]. The choice of the word "value" in these recommendations was notable, because the committee wanted to avoid the use of the word "cost-effectiveness," because this term was an anathema in certain government circles.

In considering value, it is necessary to assess the quality of the evidence as well as to define the levels of value. Although those developing cardiology guidelines are used to grading evidence, there was some discomfort with using the traditional benchmark of $50,000 per quality-adjusted life-year (QALY) gained, which seemed arbitrary and a bit out of date. Therefore, the committee adopted the framework proposed by the World Health Organization, in which interventions with an incremental cost per QALY lower than the gross domestic product (GDP) per capita should be funded, and those with a cost per QALY higher than 3 times the GDP per capita should not be funded. The proposed levels of value are presented in Table 2. A "high-value" intervention was defined as one that delivered better outcomes at lower cost, or had an incremental cost-effectiveness ratio (ICER) of less than $50,000. An intervention having an ICER of between $50,000 and $150,000 would have "intermediate value" and one with an ICER above $150,000 would have "low value" because $150,000 is around 3 times the GDP per capita for the United States. There is also an additional category for "uncertain value," when there was insufficient evidence.

The Next Steps and Remaining Challenges

The next ACC/AHA guideline will incorporate value as a part of its recommendations. This will be an evidence-based process in which published economic assessments relating to key questions will be reviewed. The Guidelines Committee, however, will not